



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 7

[Docket No. FDA-2018-D-2074]

Initiation of Voluntary Recalls; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry and FDA staff entitled “Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C.” The guidance for industry and FDA staff provides guidance on timely initiation of voluntary recalls of FDA-regulated products. It also discusses preparations that firms in a distribution chain should consider making to ensure timely responses to a recall communication. In addition, the guidance discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed products in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other laws administered by FDA. This guidance finalizes the draft guidance of the same title issued on April 24, 2019.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-2074 for "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4141, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Peter Fox, Office of Regulatory Affairs, Office of Strategic Planning and Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4146, Rockville, MD 20857, 240-402-1857, Peter.Fox@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled “Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C.” The guidance for industry and FDA staff provides guidance on timely initiation of voluntary recalls of FDA-regulated products. The guidance discusses what preparations firms in a distribution chain, including manufacturers and distributors, should consider making to establish recall initiation procedures; to ensure timely identification of, and response to, product problems that might lead to a recall; and to promptly issue recall communications and press releases or other public notices. It also discusses preparations that firms in a distribution chain should consider making to ensure timely responses to recall communications. In addition, the guidance discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed products in violation of the FD&C Act and other laws administered by FDA.

This guidance finalizes the draft guidance of the same title issued on April 24, 2019 (84 FR 17112). FDA considered comments received on the draft guidance as the guidance was finalized. In addition to editorial changes made to improve clarity, changes from the draft to the final guidance include the addition of the terms *correction* and *market withdrawal* to the terminology section, the addition of language encouraging the use of electronic communications for conveying voluntary recall communications about FDA-regulated products, and the deletion of section IV (“References”).

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not

establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 7.46, 7.49, and 7.59 have been approved under OMB control number 0910-0249; section 417 of the FD&C Act (21 U.S.C. 350f) has been approved under OMB control number 0910-0643; section 761 of the FD&C Act (21 USC 379aa-1) has been approved under OMB control number 0910-0291; 21 CFR 107.240 has been approved under OMB control number 0910-0188; 21 CFR part 117 has been approved under OMB control number 0910-0751; and 21 CFR part 507 has been approved under OMB control number 0910-0751.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>.

Dated: February 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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